

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Original) A pharmaceutical composition comprising two or more portions of solid modafinil particles from a bulk batch of modafinil, wherein each portion has a bounded particle size range and wherein one or more particle size ranges present in the bulk batch are not represented in the pharmaceutical composition.

2. (Original) A pharmaceutical composition comprising two or more portions of solid modafinil particles, wherein each portion has a bounded particle size range and wherein there is a particle size range between the size ranges represented in the two or more portions that is not represented in the pharmaceutical composition.

3. (Original) The pharmaceutical composition of claim 1 wherein more than about 5% of the particles in the composition are larger than about 200 microns.

4. (Original) The pharmaceutical composition of claim 3 wherein the composition has substantially the same dissolution profile as a modafinil composition in which at least about 95% of the particles are smaller than about 200 microns.

5. (Original) The pharmaceutical composition of claim 3 wherein the composition has substantially the same dissolution profile as PROVIGIL® (modafinil).

6. (Original) The pharmaceutical composition of claim 3 wherein at least about 80% of the modafinil dissolves after about 45 minutes.

7. (Original) The pharmaceutical composition of claim 3 wherein the composition is bioequivalent (80-125%) to a modafinil composition in which at least about 95% of the particles are smaller than about 200 microns.

8. (Original) The pharmaceutical composition of claim 3 wherein the composition is bioequivalent (80-125%) to PROVIGIL® (modafinil).

9. (Original) The pharmaceutical composition of claim 4 in which fewer than about 85% of the particles are small particles, i.e., smaller than about 200 microns.

10. (Original) The pharmaceutical composition of claim 5 in which fewer than about 85% of the particles are small particles, i.e., smaller than about 200 microns.

11. (Original) The pharmaceutical composition of claim 6 in which fewer than about 85% of the particles are small particles, i.e., smaller than about 200 microns.

12. (Original) The pharmaceutical composition of claim 7 in which fewer than about 85% of the particles are small particles, i.e., smaller than about 200 microns.

13. (Original) The pharmaceutical composition of claim 8 in which fewer than about 85% of the particles are small particles, i.e., smaller than about 200 microns.

14. (Original) The pharmaceutical composition of claim 4 in which fewer than about 75% of the particles are small particles, i.e., smaller than about 200 microns.

15. (Original) The pharmaceutical composition of claim 5 in which fewer than about 75% of the particles are small particles, i.e., smaller than about 200 microns.

16. (Original) The pharmaceutical composition of claim 6 in which fewer than about 75% of the particles are small particles, i.e., smaller than about 200 microns.

17. (Original) The pharmaceutical composition of claim 7 in which fewer than about 75% of the particles are small particles, i.e., smaller than about 200 microns.

18. (Original) The pharmaceutical composition of claim 8 in which fewer than about 75% of the particles are small particles, i.e., smaller than about 200 microns.

19. (Original) The pharmaceutical composition of claim 4 in which fewer than about 65% of the particles are small particles, i.e., smaller than about 200 microns.

20. (Original) The pharmaceutical composition of claim 5 in which fewer than about 65% of the particles are small particles, i.e., smaller than about 200 microns.

21. (Original) The pharmaceutical composition of claim 6 in which fewer than about 65% of the particles are small particles, i.e., smaller than about 200 microns.

22. (Original) The pharmaceutical composition of claim 7 in which fewer than about 65% of the particles are small particles, i.e., smaller than about 200 microns.

23. (Original) The pharmaceutical composition of claim 8 in which fewer than about 65% of the particles are small particles, i.e., smaller than about 200 microns.

24. (Original) The pharmaceutical composition of claim 4 in which fewer than about 50% of the particles are small particles, i.e., smaller than about 200 microns.

25. (Original) The pharmaceutical composition of claim 5 in which fewer than about 50% of the particles are small particles, i.e., smaller than about 200 microns.

26. (Original) The pharmaceutical composition of claim 6 in which fewer than about 50% of the particles are small particles, i.e., smaller than about 200 microns.

27. (Original) The pharmaceutical composition of claim 7 in which fewer than about 50% of the particles are small particles, i.e., smaller than about 200 microns.

28. (Original) The pharmaceutical composition of claim 8 in which fewer than about 50% of the particles are small particles, i.e., smaller than about 200 microns.

29. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 175 microns.

30. (Original) The pharmaceutical composition of claims 7 in which the small particles are smaller than about 150 microns.

31. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 125 microns.

32. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 100 microns.

33. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 75 microns.

34. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 50 microns.

35. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 25 microns.

36. (Original) The pharmaceutical composition of claim 7 in which the small particles are smaller than about 10 microns.

37. (Original) A pharmaceutical composition comprising modafinil prepared by the process of blending a first and a second portion of solid modafinil particles wherein said first portion has a pre-determined particle size range and said second portion has a pre-determined particle size range that is different from that of the first portion.

38. (Original) A pharmaceutical composition comprising at least a first and a second portion of modafinil wherein: a) the first portion of modafinil being in the form of solid modafinil particles is from a bulk batch and has a bounded particle size distribution; and b) the second portion of modafinil being in the form of solid modafinil particles from a the same or another bulk batch and has a bounded particle size distribution; wherein the combination of the first portion and the second portion yields a bounded particle size distribution that is different than the particle size distribution of the bulk batch and the other bulk batch if the other bulk batch is different from the first bulk batch.

39. (Original) The pharmaceutical composition of claim 38, wherein 95% of the cumulative total of particles in the composition are smaller than or equal to about 200 microns in diameter.

40. (Original) The pharmaceutical composition of claim 38, wherein at least one portion comprises small particles.

41. (Original) The pharmaceutical composition of claim 38, wherein at least one other portion comprises large particles.

42. (Original) The pharmaceutical composition of claim 40, wherein at least one other portion comprises very large particles.

43. (Original) The pharmaceutical composition of claim 40, wherein the first portion comprises an effective amount of modafinil.

44. (Original) The pharmaceutical composition of claim 40, wherein the first and second portion together comprise an effective amount of modafinil.

45. (Original) The pharmaceutical composition of claim 38, wherein the first and second portion comprise at least 15 milligrams of modafinil having particle diameters of between about 10 microns and 80 microns.

46. (Original) The pharmaceutical composition of claim 38, wherein the composition releases at least 80% of the modafinil in 45 minutes in a 0.1 N HCl solution.

47. (Original) A method of formulating a composition of modafinil comprising the steps of: a) providing a batch of modafinil, wherein the particles in the batch have a distribution of particle diameters; b) separating the particles in the batch of modafinil into at least two discrete lots of modafinil particles, wherein each discrete lot contains modafinil of a defined particle diameter, thereby forming at least a first discrete lot and a second discrete lot; c) blending a portion of the first lot with a portion of the second lot; and d) forming a composition of modafinil from the blend of the first lot and the second lot.

48. (Original) The method of claim 47, further comprising the step of adjusting the proportions of the first lot and the second lot in the composition to make a composition which releases at least 80% of the modafinil in 45 minutes in a 0.1 N HCl solution.

49. (Original) A pharmaceutical dosage unit comprising an effective amount of modafinil wherein at least about 10% of the total cumulative modafinil particles are smaller than about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns in diameter.

50. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 15% of the total cumulative modafinil particles are smaller than or equal to about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns.

51. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 20% of the total cumulative modafinil particles are smaller than or equal to about 25 microns

in diameter and more than about 5% of the total cumulative particles are more than about 200 microns.

52. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 25% of the total cumulative modafinil particles are smaller than or equal to about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns.

53. (Original) The pharmaceutical dosage unit of claim 48 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

54. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

55. (Original) The pharmaceutical dosage unit of claim 50 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

56. (Original) The pharmaceutical dosage unit of claim 51 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

57. (Original) The pharmaceutical dosage unit of claim 52 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

58. (Original) The pharmaceutical dosage unit of any one of claims 48-52 wherein the amount of modafinil is about 100 mg.

59. (Original) The pharmaceutical dosage unit of any one of claims 48-52 wherein the amount of modafinil is about 200 mg.

60. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

61. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

62. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

63. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

64. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

65. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

66. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

67. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

68. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

69. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

70. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

71. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

72. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

73. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

74. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

75. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

76. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

77. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

78. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

79. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

80. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

81. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

82. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

83. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

84. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

85. (Original) The pharmaceutical dosage unit of any one of claims 60-84 wherein the amount of modafinil is about 100 mg.

86. (Original) The pharmaceutical dosage unit of any of claims 60-84 wherein the amount of modafinil is about 200 mg.

87. (Original) A method of formulating a composition of modafinil comprising the steps of: a) providing a first batch and a second batch of modafinil, wherein the particles in each batch have distribution of particle diameters; b) separating the particles of the first batch of modafinil into at least two discrete lots of modafinil particles, wherein each discrete lot contains modafinil of a defined particle diameter, thereby forming at least a first discrete lot and a second discrete lot; c) recombining at least one of the discrete lots with the second batch; and d) altering the distribution of particle diameters of the particles in the second batch.

88. (Original) A pharmaceutical composition comprising at least a first and second portion of modafinil wherein: a) the first portion of modafinil being in the form of solid modafinil particles is from a bulk batch and has a bounded particle size distribution; and b) a second portion of modafinil being in the form of solid modafinil particles from the same or

another bulk batch and has a bounded particle size distribution; wherein the combination of the first portion and the second portion yields a bounded particle size distribution that is different than the particle size distribution of the bulk batch and the other bulk batch if the other bulk batch is different from the first bulk batch, and wherein the particle size distribution of the first batch is at least one particle size distribution selected from the group consisting of $0.01 \leq P \leq 200$, $0.01 \leq P \leq 40$, $40 \leq P \leq 80$, $80 \leq P \leq 120$, $120 \leq P \leq 160$, $160 \leq P \leq 200$, $0.01 \leq P \leq 10$, $10 \leq P \leq 20$, $20 \leq P \leq 30$, $30 \leq P \leq 40$, $40 \leq P \leq 50$, $50 \leq P \leq 60$, $60 \leq P \leq 70$, $70 \leq P \leq 80$, $80 \leq P \leq 90$, $90 \leq P \leq 100$, $100 \leq P \leq 110$, $110 \leq P \leq 120$, $120 \leq P \leq 130$, $130 \leq P \leq 140$, $140 \leq P \leq 150$, $150 \leq P \leq 160$, $160 \leq P \leq 170$, $170 \leq P \leq 180$, $180 \leq P \leq 190$, and $190 \leq P \leq 200$.

89. (Original) The pharmaceutical composition of claim 88, wherein the particle size distribution of the second batch is at least one particle size distribution selected from the group consisting of $220 < P \leq 400$, $220 < P \leq 310$, $310 \leq P \leq 400$, $220 < P \leq 230$, $230 \leq P \leq 240$, and $240 \leq P \leq 250$, $250 \leq P \leq 260$, $260 \leq P \leq 270$, $270 \leq P \leq 280$, $280 \leq P \leq 290$, $290 \leq P \leq 300$, $300 \leq P \leq 310$, $310 \leq P \leq 320$, $330 \leq P \leq 340$, $340 \leq P \leq 350$, $350 \leq P \leq 360$, $360 \leq P \leq 370$, $370 \leq P \leq 380$, $380 \leq P \leq 390$, and $390 \leq P \leq 400$.

90. (Original) A pharmaceutical composition manufactured by the steps comprising:
a) preparing a bulk batch; and b) removing at least one discrete lot of particles having a bounded particle size range from the bulk batch.

91. (Original) A pharmaceutical composition obtained from a bulk batch of modafinil, wherein the pharmaceutical composition has a particle size distribution that is different from the particle size distribution of the bulk batch.

92. (Original) The pharmaceutical composition of claim 88, further comprising a surfactant.

93. (Original) The pharmaceutical composition of claim 92, wherein the surfactant is selected from the group consisting of non-ionic, ionic, and bile salt surfactants.

94. (Original) The pharmaceutical composition of claim 92, wherein the surfactant is the ionic surfactant sodium dodecyl sulfate.

95. (Original) The pharmaceutical composition of claim 92, wherein the surfactant is a non-ionic surfactant selected from the group consisting of polyoxethylene stearates and block copolymers of ethylene oxide and propylene oxide.

96. (Original) The pharmaceutical composition of claim 92, wherein the surfactant is a bile salt surfactant selected from the group consisting of sodium cholate, sodium taurocholate and sodium deoxycholate.

97. (Original) A method of altering the somnolent state of a mammal, said method comprising administering an effective amount of the composition of claim 1 to said mammal.

98. (Original) A method for enhancing alertness or increasing regularity of sleep rhythms in a mammal said method comprising administering an effective amount of the composition of claim 1 to said mammal.

99. (Original) A method of treating a mammal diagnosed with a modafinil-responsive disease or condition selected from the group consisting of narcolepsy, sleepiness, excessive sleepiness, excessive daytime sleepiness associated with narcolepsy, Parkinson's disease, urinary incontinence, multiple sclerosis fatigue, ADHD, Alzheimer's disorder, sleep apnea, obstructive sleep apnea, depression, and ischemia, said method comprising administering an amount of modafinil, as one or more oral unit doses, to said mammal, said oral unit doses comprising an effective amount of the composition of claim 1.

100. (Original) A composition comprising two or more portions of solid modafinil particles from a bulk batch of modafinil, wherein each portion has a bounded particle size range and wherein one or more particle size ranges present in the bulk batch are not represented in the pharmaceutical composition.

101. (Original) A composition comprising two or more portions of solid modafinil particles, wherein each portion has a bounded particle size range and wherein there is a particle size range between the size ranges represented in the two or more portions that is not represented in the pharmaceutical composition.

102. (Original) The composition of claim 100 wherein more than about 5% of the particles in the composition are larger than about 200 microns.

103. (Original) The composition of claim 102 wherein the composition has substantially the same dissolution profile as a modafinil composition in which at least about 95% of the particles are smaller than about 200 microns.

104. (Original) The composition of claim 102 wherein the composition has substantially the same dissolution profile as PROVIGIL® (modafinil).

105. (Newly added) A process for preparing an oral dosage form containing modafinil particles, the process comprising:

forming a dosage form comprising

more than about 5% of the modafinil particles in the dosage form have diameters greater than about 200 microns; and

less than about 95% of the modafinil particles in the dosage form have diameters less than about 200 microns.

106. (Newly added) A process for preparing an oral dosage form containing modafinil particles, the process comprising:

forming a dosage form comprising about 5% to about 35% modafinil particles more than 220 microns in diameter, and about 95% to about 65% modafinil particles less than 220 microns in diameter.

107. (Newly added) The process according to claim 106 wherein about 10% to about 30% of the modafinil particles are more than 220 microns in diameter.

108. (Newly added) The process according to claim 107 wherein about 15% to about 30% of the modafinil particles are more than 220 microns in diameter.

109. (Newly added) The process according to claim 108 wherein about 20% to about 30% of the modafinil particles are more than 220 microns in diameter.

110. (Newly added) The process according to claim 109 wherein about 25% to about 30% of the modafinil particles are more than 220 microns in diameter.

111. (Newly added) The process according to claim 106 wherein about 20% of the modafinil particles are more than about 250 microns in diameter, and about 80% of the particles are between about 10 microns and 100 microns in diameter.

112. (Newly added) The process according to claim 106 wherein the dosage form is a tablet or capsule.

113. (Newly added) The process according to claim 106 wherein forming the dosage form comprises blending the modafinil particles with one or more pharmaceutically inert excipient to form a blend and compressing the blend or filling the blend into a solid dosage form.

114. (Newly added) The oral dosage form prepared according to a process of any one of claims 105 to 113.

115. (Newly added) An oral dosage form of modafinil wherein:
more than about 5% of the modafinil particles in the dosage form have diameters greater than about 200 microns; and

less than about 95% of the modafinil particles in the dosage form have diameters less than about 200 microns.

116. (Newly added) The oral dosage form according to claim 115 wherein about 5% to about 35% of the modafinil particles are more than 220 microns in diameter, and about 95% to about 65% of the modafinil particles are less than 220 microns in diameter.

117. (Newly added) The oral dosage form according to claim 116 wherein about 10% to about 30% of the modafinil particles are more than 220 microns in diameter.

118. (Newly added) The oral dosage form according to claim 117 wherein about 15% to about 30% of the modafinil particles are more than 220 microns in diameter.

119. (Newly added) The oral dosage form according to claim 118 wherein about 20% to about 30% of the modafinil particles are more than 220 microns in diameter.

120. (Newly added) The oral dosage form according to claim 119 wherein about 25% to about 30% of the modafinil particles are more than 220 microns in diameter.

121. (Newly added) The oral dosage form according to claim 116 wherein about 20% of the modafinil particles are more than about 250 microns in diameter, and about 80% of the modafinil particles are between about 10 microns and 100 microns in diameter.

122. (Newly added) The oral dosage form according to claim 116 wherein the dosage form is a tablet or capsule.

123. (Newly added) The oral dosage form according to claim 122 further comprising one or more pharmaceutically acceptable excipient.

124. (Newly added) The oral dosage form according to claim 116 wherein the dosage form has substantially the same dissolution profile as PROVIGIL® (modafinil).

125. (Newly added) The method of treating a condition using modafinil, the method of treating comprising:

providing an oral dosage form according to any one of claims 115 to 124.

126. (Newly added) The method according to claim 125, wherein said condition comprises one or more of narcolepsy and idiopathic hypersomnia.